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LISA A HAILE PH D  
GRAY CARY WARE AND FREIDENRICH LLP  
4365 EXECUTIVE DRIVE SUITE 1600  
SAN DIEGO, CA 92121-2189

EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/19/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/342,024

Applicant(s)

NOLAN ET AL.

Examiner

Gerald Leffers

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 3, 13-16, 18 and 23-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-12, 19, 20, 30, 31, 34, 36, 37 and 39 is/are rejected.
- 7) ☒ Claim(s) 17, 21-22, 32-33, 35, 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1636

### **DETAILED ACTION**

Receipt is acknowledged of applicants' amendment, filed 4/08/02 as Paper No. 12. In Paper No. 12 several claims were amended (claims 1, 5, 8, 19-22) and several new claims were added (claims 30-39). Claims 1-39 are pending in this application with claims 3, 13-16, 18 and 23-29 withdrawn from consideration as being drawn towards nonelected inventions.

Any rejection of record in Paper No. 8 that has not been addressed in this action has been withdrawn.

### ***Information Disclosure Statement***

Receipt is acknowledged of information disclosure statements filed 3/5/02 and 4/8/02 (Paper Nos. 9 and 11, respectively). The signed and initialed PTO Form 1449s have been mailed with this action.

### ***Claim Objections***

Claims 4 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitations recited in these claims are already present in claim 1, upon which these claims are dependent.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-2, 4-11, 19-20 rejected under 35 U.S.C. 102(e) as being anticipated by Dev et al (U.S. Patent No. 5,944,710; see the entire patent). **This rejection is maintained for reasons of record in Paper No. 8, mailed 10/2/01 and repeated below. The rejection is extended to new claims 30, 31, 34, 36, 37 and 39.**

The Dev et al patent (the '710 patent) teaches compositions and methods for the sustained intravascular delivery via electroporation of therapeutic compositions (Abstract). The therapeutic compositions of the invention include nucleic acids such as plasmids or anti-sense oligonucleotides against c-myc or c-myb (column 3, line 21; column 5, lines 15-21). The electric fields needed for in vivo cell electroporation according to the invention can range from 100V/cm to several kV/cm (column 10, lines 1-9). The waveforms of the voltage pulse provided by the generator in the power pack can be exponentially decaying pulse, square pulse, unipolar oscillating pulse train or bipolar oscillating pulse train (column 10, lines 55-60) The pulse length can be 100 microseconds to 100 milliseconds, preferably from about 500 microseconds to 10 milliseconds. From about 1 to 10 pulses can be applied to an area or group of cells (column 11, lines 5-10). A gene transfer experiment is exemplified wherein a standard marker gene, lacZ

Art Unit: 1636

driven by a CMV promoter, was injected into an artery followed by electroporation (three pulses at 10 second intervals at 76 V and .76 milliseconds) (column 14, lines 15-49). The '710 patent teaches that the composition comprising DNA can be administered by gradual perfusion, intravenously, intraperitoneally, intramuscularly, subcutaneously, intracavity, transdermally or intravascularly near the site of electroporation (column 6, lines 19-24).

### ***Response to Arguments***

Applicant's arguments filed in Paper No. 12 have been fully considered but they are not persuasive. While conceding that the parameters disclosed by Dev et al overlap with the range specified in the instant claims, the response essentially argues that Dev et al do not teach the specific ranges, or combination of specific ranges, recited in the instant claims. The response specifically points to the example wherein a pulse length of only .76 milliseconds was used. While it is true that the example cited by the examiner (i.e. .76 milliseconds) is no longer directly applicable to the amended claims, it is clear from the teachings of the Dev et al patent that the cited ranges of 100-2,000 V/cm and .1-100 milliseconds were clearly intended for use in electroporating mammalian cells. Even if one accepts the narrower range taught by Dev et al of .5-5 kV, this still falls within the range specified in the rejected claims.

Claims 1-2, 4-12, 19-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamazaki et al (Biology of Reproduction, December 1998, Vol. 59, pages 1439-1444; see the entire reference). **This rejection is maintained for reasons of record in Paper No. 8, mailed 10/2/01 and repeated below. This rejection is extended to new claims 30, 31, 34.**

Yamazaki et al teach a method for in vivo gene transfer to mouse spermatogenic cells comprising DNA injection into seminiferous tubules and subsequent electroporation. The authors teach their method provides a convenient assay for gene expression during spermatogenesis (i.e. expression in dividing cells). The 2 month duration of marker expression in some cell types indicate that spermatogenic stem cells (i.e. nondividing cells) and/or spermatogonia could also incorporate foreign DNA and that the transgene could be transmitted to progenitor cells derived from transfected germ cells (Abstract). The electroporation methods of the invention comprised intratubular or interstitial injection of Qiagen Maxi column-purified plasmid DNAs into the testes followed by electroporation. The electroporation conditions comprised holding the testes between tweezer-type electrodes and application of square electric pulses eight times at 20-50 V with a constant time of 50 milliseconds (page 1440, in vivo EP paragraph). One of skill in the art would necessarily conclude upon reading the teachings of Yamazaki et al that the electronic field pulse used constitutes a "low" electronic field pulse and that the 50 millisecond pulse duration constitutes a "long duration". For example, the testes shown in Figure 1 are ~2-3 mm in diameter, indicating a gap of ~.2-.3 cm and a probable field strength of ~250 V/cm. It is noted that the relative term "about" is not clearly defined in relation to field strength or electronic pulse duration (e.g. "about" 300-600 V/cm or "about" 10 to 100 milliseconds).

#### ***Response to Arguments***

Applicant's arguments filed in Paper No. 12 have been fully considered but they are not persuasive. The response argues that the reference is not prior art because the instant application claims priority to USSN 09/103,477, filed on June 24, 1998, now abandoned. This argument is

Art Unit: 1636

not persuasive in that there is no claim for priority to USSN 09/103,477 in the instant application. The rejection stands.

### *Conclusion*

No claims are allowed. Claims 1-39 are pending in this application with claims 3, 13-16, 18 and 23-29 withdrawn from consideration as being drawn towards nonelected inventions. Claims 1-2, 4-12, 30-31, 34, 36-37 and 39 are rejected. Claims 17, 21-22, 32-33, 35 and 38 are objected to as being dependent upon rejected claims. These claims would be allowable if rewritten in independent form comprising each of the limitations of the claims from which they are currently dependent.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.  
Examiner  
Art Unit 1636

AA2

ggl  
June 16, 2002

DAVID GUZO  
PRIMARY EXAMINER  
